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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,262	03/25/2002	Alessandro Seneci	TRUF101	2926

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/089,262

Applicant(s)

SENECI ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The lettering of the steps in Claim 5 suggest that they are further steps to be carried out after completing the steps disclosed in Claim 1. However, it appears that the steps are rather more narrowly defined steps to those presented in Claim 1, and in order to advance prosecution, the steps of the claim will be treated as such. Nevertheless, clarification of the steps is requested.

Claim 5 also recites the limitation “said excipients and/or adjuvants” in the second and third lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 also recites the limitation “said at least one fat and/or phospholipid” in the fourth and fifth lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 also recites the limitations “at least one fat” and “excipients and/or adjuvants” in the third line of the claim. As Claim 10 ultimately depends upon Claim 1, there is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

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explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 5 recites the broad recitation "5-20°C", and the claim also recites "preferably to 10°C-12°C", which is the narrower statement of the range/limitation. Claim 5 also recites the broad recitation "between 1 and 4 mm", and the claim also recites "preferably 1 and 2 mm", which is the narrower statement of the range/limitation.

Claim 7 recites the broad recitation "between 3 and 20 carbon atoms", and the claim also recites "preferably between 14 and 18 carbon atoms", which is the narrower statement of the range/limitation.

Claim 5 recites the broad recitation "70-95%", and the claim also recites "preferably 75-90%", which is the narrower statement of the range/limitation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palepu *et al.* (U.S. Patent No. 5,824,344)

The Palepu *et al.* patent teaches a process for preparing controlled-release dosage forms (See Column 3, Lines 48-52). Types of dosage forms include controlled-release granules that are suitable for compression into tablets (See Column 4, Lines 20-25; Column 7, Line 64 to Column 8, Line 21). The granules comprise a hydrophobic waxy material that is defined as a fatty acid, alcohol, ester, or combinations thereof. The fatty acid may have from about 10 to about 22 carbon atoms, including palmitic acid. Although glyceryl behenate is given as a referred material, partially hydrogenated vegetable oils, including palm oil, may be used to fully substitute for glyceryl behenate (See Column 8, Lines 22-27; and Column 12, Lines 10-13). Cimetidine, a histamine H<sub>2</sub>-receptor antagonist, is given as a suitable active ingredient for the disclosed dosage forms (See Column 6, Lines 22-42). An example is given in which two formulations of cimetidine are given, comprising cimetidine, glyceryl behenate, and microcrystalline cellulose in amounts of approximately 57.6%, 30.1%, and 12.5% by weight, respectively, and 70.0%, 15.0%, and 15.0% by weight, respectively (See Example 6). Other embodiments include compositions containing active ingredients in amounts of about 50% to 98% by weight or from 20% to 80% by weight. Processes include steps of sizing particles from about 50 microns to about 1000 microns; heating and then cooling to ambient temperatures; and compressing granules into tablets. Excipients that may be used include microcrystalline cellulose and colloidal silicon dioxide (See Column 9, Line 65 to Column 11, Line 17).

It would be obvious to one of ordinary skill in the art that through the course of routine experimentation, the disclosed process of Palepu *et al.* can be adapted to the instantly claimed

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invention. Although the granules described in Palepu *et al.* are made by a thermal infusion process, melt granulation methods are disclosed as being known in the art (See Column 1, Line 60 to Column 2, Line 22). The Palepu *et al.* also does not specifically a cooling step wherein the process temperature is reduced to the range of 5°C to 20°C. However, it is the position of the examiner that such a step would be attainable through routine experimentation. The burden is shifted onto the applicant to provide a showing of criticality or of unexpected results that would be beyond the purview of one of ordinary skill in the art at the time the instantly claimed invention was made. Additionally, the examiner does not see a patentable distinction in the disclosure in Palepu *et al.* regarding the selection of a partially hydrogenated palm oil, rather than a hydrogenated palm oil. It is the position of the examiner that the specific selection between a partially hydrogenated palm oil and a hydrogenated palm oil would be obvious to one of ordinary skill in the art.

Thus, the instantly claimed invention is *prima facie* obvious.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj  
April 15, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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